September 7, 2018

Coloplast A/S
Cori L. Ragan
Regulatory Affairs Manager
1601 West River Road North
Minneapolis, MN 55411

Re: K181811
Trade/Device Name: ReTrace Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: August 7, 2018
Received: August 8, 2018

Dear Cori L. Ragan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181811

Device Name
ReTrace Ureteral Access Sheath

Indications for Use *(Describe)*
The ReTrace Ureteral Access Sheath is used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7. SPECIAL 510(k) SUMMARY

I. SUBMITTER

510(K) Owner's Name: Coloplast A/S

Legal Manufacturer Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Phone: (612) 597-5106
Email: usclr@coloplast.com

Name of Contact Person: Cori L. Ragan
Regulatory Affairs Manager

Address/Contact: 1601 West River Road
Minneapolis, MN 55411

Date Prepared: June 28, 2018

II. DEVICE

Trade or Proprietary Name: ReTrace® Ureteral Access Sheath

Common or Usual Name: Endoscopic Access Overtube, Gastroenterology-Urology

Classification Name: Endoscope and Accessories
(21 CFR section 876.1500)
Product Code: FED
Device Class: 2

Classification Panel: Gastroenterology-Urology

III. PREDICATE DEVICE

The proposed additional lengths of the ReTrace Ureteral Access Sheath are substantially equivalent in performance, indication, design, and materials to the Coloplast's own predicate device, ReTrace Ureteral Access Sheaths cleared under 510(k) K140523 and K123675.

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ReTrace Ureteral Access Sheath is comprised of the following components:

- Reinforced tube/sheath
- Introducer/dilator
- Connector
- Clip

The reinforced polymeric introducer sheath includes a hydrophilic coating on the exterior and a lubricious inner surface. The sheath is reinforced to provide kink resistance. The distal tip of the sheath is fitted with a radiopaque ring. A white connector and orange clip is fitted on the proximal end of the sheath.

The introducer is fitted with a Luer connector on the proximal end and has a hydrophilic coating on the distal end. A guidewire entry and exit eye and exit holes for fluid delivery are located at the distal end of the introducer.

This submission expands the product line to include 28 cm long and 55 cm long sheaths with inner diameters of 10 and 12 Fr.

V. INDICATIONS FOR USE

The modified ReTrace Ureteral Access Sheaths have the same intended use as the previously cleared models which is as follows:

> The ReTrace Ureteral Access Sheath is used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified ReTrace Ureteral Access Sheath is substantially equivalent in performance, indication, design, and materials to the previously cleared, ReTrace Ureteral Access Sheath (K140523 and K123675).

Technological Characteristic	**ReTrace Ureteral Access Sheath (Subject Device)**	**Retrace Ureteral Access Sheath - K140523 (Predicate Device)**	**Retrace Ureteral Access Sheath – K123675 (Predicate Device)**
Design	Access Sheath with introducer	Same	Same
Sizes	10 FR Inner Diameter (ID) / 12 FR Outer Diameter (OD) and 12 FR ID / 14 FR OD	12 FR ID / 14 FR OD	10 FR ID / 12 FR OD and 12 FR ID / 14 FR OD
Length	28cm and 55cm	35 and 45cm	35 and 45cm
Length of dilator out of sheath	5 cm	5 cm	5 cm 2 cm
Insertion Technique	Insertion over a guidewire	Same	Same
Device Materials	PEBA, PTFE, stainless steel, PVC, polycarbonate, Nitinol	Same	Same
Coating	Hydrophilic coating	Same	Same
Single use	Yes	Same	Same
Sterility	Ethylene Oxide Sterilized	Same	Same
Shelf Life	5 years	Same	2 years

VII. PERFORMANCE DATA

The following testing data was provided in support of the substantial equivalence determination and changes to the product line.

Biocompatibility Testing

No additional biocompatibility testing was provided.

Mechanical Testing

Mechanical testing was completed in support of the substantial equivalence determination and changes to the product line.

- Visual
- Dimensional verification
- Guidewire pullout force
- Device integrity and functionality
- Simulated use
- Viscous fluid
- Kink resistance
- Shelf life testing to support 5 years

Sterilization

The ReTrace Ureteral Sheaths are sterilized using ethylene oxide in a validated cycle demonstrating a microbial assurance level of 10^{-6}.

Packaging and Distribution

No additional packaging or distribution testing was provided.

No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The additional lengths of the ReTrace Ureteral Access Sheath have been demonstrated to be substantially equivalent to the predicate, ReTrace Ureteral Access Sheath, based on the non-clinical data provided. The test results demonstrate that the additional models do not raise new questions of safety or effectiveness and are substantially similar to the ureteral access sheaths cleared as ReTrace Ureteral Access Sheaths in K140523 and K123675.